IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE

METHODIST HEALTHCARE – MEMPHIS HOSPITALS, Plaintiff, v. XAVIER BECERRA, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES Defendant.	:	No. _____

COMPLAINT FOR JUDICIAL REVIEW

Plaintiff Methodist Healthcare – Memphis Hospitals ("Methodist" or "Plaintiff"), by and through undersigned counsel, files this Complaint for Judicial Review against Defendant Xavier Becerra, in his official capacity as the Secretary of the United States Department of Health and Human Services ("Secretary" or "Defendant"), following the final agency decision of the Medicare Appeals Council ("Council") as to Council docket number M-21-1642 and Administrative Law Judge (ALJ) appeal number 3-3427161631. In support of its Complaint, Methodist states as follows:

PARTIES

1. Plaintiff Methodist Healthcare - Memphis Hospitals is a corporation organized under the laws of the State of Tennessee, with its principal place of business in this judicial district.

2. Defendant Xavier Becerra is the Secretary of the United States Department of Health and Human Services and is the proper defendant in this action pursuant to 42 C.F.R. §405.1136(d)(1).

JURISDICTION AND VENUE

3. Jurisdiction is proper pursuant to 42 U.S.C. §1395ff(b), which authorizes judicial review of a final agency decision of the Secretary.

4. Venue is proper pursuant to 42 U.S.C. §1395ff(b) and 405(g) as Plaintiff's principal place of business is located in this judicial district.

5. The amount in controversy exceeds the jurisdictional amount set forth in 42 U.S.C. §1395ff(b)(E)(i).

6. This action has been commenced within sixty (60) days of Methodist's notification of the final agency decision, as mandated by 42 C.F.R. §§405.1130, 1136(c)(1).

7. Methodist has exhausted all administrative remedies and is appealing a final administrative decision.

FACTUAL BACKGROUND

Medicare Payment for Inpatient Hospital Services

8. At all times relevant hereto, Methodist provided inpatient and outpatient hospital services to patients, some of whom are Medicare beneficiaries.

9. Medicare is a federal health insurance program for the elderly and disabled that was established in 1965. The Medicare statute is codified at 42 U.S.C. §1395 *et seq.*

10. One of the benefits available to Medicare beneficiaries under Part A of the program is up to 90 days of coverage for inpatient hospital services for any one episode of

illness. 42 U.S.C. §1395d(a)(1). The decision to admit a patient as an "inpatient" is made by a physician or other practitioner responsible for a patient's care at the hospital. 42 C.F.R. § 412.3.

11. The Centers for Medicare and Medicaid Services ("CMS") has provided guidance as to whether inpatient services are covered by the Medicare program in its Medicare Benefit Policy Manual. If inpatient services are not covered, these same services may be payable as outpatient hospital services under Part B of the Medicare program, or may not be payable by Medicare at all.

12. Inpatient hospital care is generally paid for by Medicare as bundled services based on prospective payment, not individual line item payment. To receive payment, a hospital must classify its eligible discharges into Diagnosis Related Groups ("DRG") based on the anticipated expenditure of resources by the hospital. The hospital is then paid based on the DRGs assigned to the patients. Medicare provides guidance to providers regarding DRGs in the Medicare Program Integrity Manual ("MPIM").

13. Medicare's payment and audit functions are performed by various federal contractors. Various other contractors investigate instances of suspected fraud, waste, and abuse as well as identify any payments not made pursuant to Medicare billing guidelines that are collected by providers (often referred to as "overpayments"). Audits and investigations are also performed by the Office of Inspector General for the Department of Health and Human Services ("OIG").

14. Over the past decades, a part of this process has involved use of statistical sampling to extrapolate an overpayment assessment based upon individual audited patient accounts. CMS has issued a ruling describing the agency's policy on the use of statistical sampling to project such overpayments to Medicare providers. CMS Ruling 86-1. Sampling

does not deprive a provider of its rights to challenge the validity of the sampling and extrapolation, nor of its rights to procedural due process regarding the process. CMS guidelines as set forth in the MPIM address the use of statistical sampling. The statistical sampling and extrapolation process must be statistically valid.

15. As generally described in the MPIM, a basic prerequisite of a valid process for statistical sampling involves the contractor following a procedure that results in a "probability sample." Although only one sample will be selected, each distinct sample of the set must have a known probability of selection. Each sampling unit in each distinct possible sample must also have a known probability of selection. Expressed another way, regardless of the specific methodology chosen by the contractor, the probability of the sample being selected can't be zero.

Procedural History and Basis of Appeal

16. In 2013 as it does with health care systems across the country, the OIG initiated an audit of Methodist's inpatient billings to Medicare. The applicable time frame for the audit was January 10, 2011 to June 6, 2012.

17. Through the use of a contractor, the OIG identified 3,590 Medicare paid claims out of an inpatient universe of more than 15,000 to be the subject of its audit. It then selected a sample of 150 of those claims to be reviewed for Medicare coverage and payment purposes.

18. The OIG's Sample Design and Methodology for purposes of extrapolation defined "audit" to exclude claims previously reviewed by a Medicare Recovery Audit Contractor ("RAC"). Contrary to the OIG's stated methodology, however, the claims reviewed as part of the audit which is the subject of this case included RAC claims. Specifically, one of the claims in the selected patient sample of 150 claims was a RAC claim, and seven additional RAC claims were included in the sampling "frame."

19. Of the 150 claims reviewed as part of the audit, the OIG found 102 of those claims to be fully compliant with Medicare billing guidelines. The OIG then extrapolated the average alleged overpayment amount from the 48 remaining claims to the original universe of claims, from which it calculated a purported $5,893,302.00 "overpayment" to Methodist. The OIG's final audit report outlining its findings was issued in October 2014.

20. Methodist appealed the OIG's findings as to 27 of the purportedly inappropriately paid claims to Novitas Solutions, the Medicare Administrative Contractor ("MAC"). Several claims that were not appealed were instead rebilled and paid as Medicare Part B services. In addition to challenging the determinations for 27 claims, the appeal challenged the validity of the statistical sampling methodology and implementation of the methodology used by the OIG on multiple grounds. Methodist submitted an opinion from a statistical expert in support of its challenge to the sampling process, as to which no response was filed. The MAC upheld the statistical sampling methodology and did not reverse any of the OIG's findings on individual cases. The MAC, in fact, recalculated the overpayment assessment so that it increased to $6,098,371.00.

21. Methodist requested reconsideration of the MAC's decision at the next level of the Medicare administrative appeals process, the Qualified Independent Contractor ("QIC"), Maximus Federal Services, Inc. Methodist's reconsideration appeal again challenged both certain claim denials and the validity of the statistical sampling process used in this case. It included a report from a second statistical expert outlining multiple bases for invalidating the sampling. In its reconsideration decision, the QIC found 5 of the 27 appealed claims met Medicare coverage guidelines, resulting in a modified extrapolated overpayment of $4,948,753. The recalculation did not address claims in the sample paid under Medicare Part B. The QIC

upheld the validity of the statistical sampling process used by the OIG. Acting pursuant to its regulatory authority, CMS "recouped" this overpayment assessment from Methodist by withholding Medicare payments in that amount from the hospital's Medicare reimbursements.

22. Methodist further appealed the remaining 22 claims by requesting a hearing before an Administrative Law Judge ("ALJ") in the Office of Medicare Hearings and Appeals. In addition to challenging the OIG's findings as to the remaining claims, Methodist reasserted its challenge to the validity of the statistical sampling process performed by the OIG contractor in the audit. Methodist presented testimony and/or reports from three statistical experts regarding the invalidity of the OIG's sampling process, in addition to providing testimony and argument on the medical necessity and proper coding of the specific claims at issue. The ALJ hearing, at which the contractor did not appear and no testimony supporting the OIG extrapolation process or implementation was submitted, was held on June 11, 2020.

23. Based on the evidence submitted, the Honorable LaSandra Morrison ("ALJ Morrison") issued a partially favorable Decision to Methodist on December 15, 2020 ("ALJ Decision," attached at **Exhibit A**). In her decision, ALJ Morrison found that 9 of the 22 remaining claims satisfied Medicare's coverage and payment requirements, and that one claim had only been partially overpaid.

24. ALJ Morrison additionally found that the OIG's statistical and extrapolation process did not comply with section 1893 of the Social Security Act (42 U.S.C. § 1395ddd) and the MPIM's guidance on statistical sampling and extrapolation. This finding was based on only one of a number of grounds of impropriety in OIG's statistical process that was raised by Methodist in its appeal: the fact that by including RAC claims in the sampling frame and sample set of 150 claims, the OIG had not followed its own defined audit definition and had failed to

obtain a valid probability sample in violation of applicable requirements. At the hearing, two Methodist experts, without contradiction, testified that the presence of such claims outside the audit definition made it impossible to obtain a valid statistical sample because such claims, by definition, should not have been available to be sampled if the audit definition had been followed. ALJ Morrison agreed with Methodist's experts that "[a]n error of this magnitude contaminates the entire sampling process" and "invalidates the proposed extrapolation." ALJ Decision at 12. ALJ Morrison concluded:

> A sampling frame that includes data outside the definition of an audit cannot be re-created, thus invalidating the extrapolation based on the sample drawn. OIG failed to follow the agency's rules for performing statistical sampling. Specifically, the sampling frame and sample design employed by OIG did not meet the requirements of the MPIM. *Id*.

25. The ALJ Decision did not address the other sampling and implementation deficiencies identified by Methodist.

26. On February 16, 2021, the Administrative Qualified Independent Contractor ("AdQIC"), acting on behalf of CMS, referred the ALJ Decision and the related claim files to the Medicare Appeals Council ("Council") – the final level of administrative review for the extrapolated overpayment claim -- for possible review on the Council's own motion. Because neither CMS nor any of its contractors participated in the ALJ hearing, the Council's authority to accept its own motion review was limited to a material error of law or a broad policy or procedural issue that may affect the general public interest. 42 C.F.R. § 405.1110(c). The referral was based solely upon the ground relied upon by the ALJ to find the statistical sampling process invalid. Neither the AdQIC nor Methodist challenged the ALJ's determinations on the individual claims appealed.

27. Methodist filed timely exceptions to the AdQIC's referral on March 18, 2021, contesting the substance of the AdQIC's referral, as well as whether the referral met the standard for Council review.

28. The Council reversed in part the ALJ Decision. ("Council Decision," attached at **Exhibit B**). The Council Decision considered the issue of the validity of the sampling process to be a legal and not a factual issue. It found that the record supported OIG's statistical and extrapolation process, despite not being consistent with the OIG's own audit definition, and the undisputed expert testimony submitted by Methodist addressing several other aspects of the flawed implementation of the extrapolation process. The Council decision was that the extrapolation met all applicable Medicare legal and regulatory requirements regarding statistical extrapolation. The Council Decision left all findings of the ALJ Decision concerning individual claims intact.

29. The Council Decision is the Secretary's final agency determination.

CLAIMS FOR RELIEF

Count I

30. Methodist hereby incorporates by reference paragraphs 1 through 29 herein.

31. Based upon the record developed before the MAC, QIC, ALJ and Council (hereinafter the "administrative record"), the Council Decision is unlawful and erroneous, and should be set aside on the grounds that the final agency action is arbitrary, capricious, an abuse of discretion, improper resolution of a fact issue, or otherwise not in accordance with law.

Count II

32. Methodist hereby incorporates by reference paragraphs 1 through 31 herein.

33. Based upon the administrative record, the Council Decision is contrary to constitutional right, power, privilege or immunity, violating Methodist's due process rights.

Count III

34. Methodist hereby incorporates by reference paragraphs 1 through 33 herein.

35. Based upon the administrative record, the Council Decision, in reversing a factual determination not only well established in the record at the ALJ level, but being undisputed as well, is in excess of statutory jurisdiction, authority, and limitations and short of statutory right.

Count IV

36. Methodist hereby incorporates by reference paragraphs 1 through 35 herein.

37. Based upon the administrative record, the Council Decision is without observance of procedure required by law.

Count V

38. Methodist hereby incorporates by reference paragraphs 1 through 37 herein.

39. Based upon the administrative record, the Council Decision is unsupported by substantial evidence as required by law.

PRAYER FOR RELIEF

WHEREFORE, Methodist respectfully requests that this Court:

a) Reverse the decision of the Council and find that OIG's statistical and extrapolation process utilized in its audit was invalid and violated applicable law and regulations;

b) Order the Secretary to recalculate the assessed overpayment related to OIG's audit consistent with the determinations made in the ALJ Decision;

c) Grant to Methodist its reasonable attorneys' fees and costs;

d) Grant to Methodist any other legal or equitable relief that the Court may deem just and proper.

Respectfully submitted,

/s/ Buckner Wellford
Buckner Wellford
TN Bar No. 09687
Baker, Donelson, Bearman, Caldwell & Berkowitz P.C.
First Horizon Building
165 Madison Avenue
Suite 2000
Memphis, TN 38103
(901) 577-2152
bwellford@bakerdonelson.com

Counsel for Methodist Healthcare – Methodist Hospitals